REMARKS

Upon entry of the instant amendment, claims 30-43 are currently being examined. Claims 1-29 are cancelled. The cancellation of claims 1-29 is not to be construed as an admission by Applicant or Applicant's Agent that such claims are not patentable, and Applicant reserves the right to pursue the subject matter of the cancelled claims in a divisional or continuing application. Claims 30-43 have been added. Support for the claims can be found, for example, on page 4, lines 4-7 and lines 25-30; and on page 7, lines 13-18 of the specification. Thus, no new matter has been added.

Objection of the Specification

The Examiner has objected to the specification for failing to provide adequate written description and failing to adequately teach how to make or use the invention. *See*, Office Action page 3.

Applicants traverse this objection. The reasons for the traversal are argued below under the section Rejections under 35 U.S.C. § 112, first paragraph. In view of the remarks below, Applicant respectfully requests that the Examiner reconsider and withdraw the objection to the specification.

Rejection under 35 U.S.C. § 112

A. The Examiner has rejected Claims 1-5, 7, 9-11, 13-16, 19 and 20 under 35 U.S.C. § 112, first paragraph. In particular, the Examiner states "the specification, while being enabling for combinations of neutralizing anti-respiratory syncytial virus (RSV) F antigen antibodies with anti-viral agents, does not reasonably provide written description and enablement for compositions comprising any and every anti-microbial neutralizing antibody, or undisclosed variants of fragments thereof, with any and every anti-microbial agent." *See*, Office Action page 3.

Applicant respectfully disagrees and traverses this rejection. However, in order to expedite prosecution, Applicant has cancelled claims 1-29 and added claims 30-43. The

new claims recite that "...at least one anti-RSV neutralizing antibody and at least one additional non-antibody anti-viral agent, wherein said composition prevents RSV infection." As the Examiner has pointed out, the specification is enabling for combinations of neutralizing anti-respiratory syncytial virus (RSV) F antigen antibodies with anti-viral agents. *See*, Office Action page 3. Also, the examiner has acknowledged that the specification provides "guidance" for anti-RSV antibodies. *See*, Office Action page 4. In view of the forgoing Applicant believes that the rejection has been obviated and, thus, Applicant respectfully requests that rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. The Examiner has rejected claims 1-7, 9-16, 19, 20 and 27 under 35 U.S.C. § 112, second paragraph, as alleging indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *See*, Office Action page 5. In particular, the Examiner asserts that the recitation of "including...variants or fragments thereof" is not clear as to what or how many antibodies including variants or fragments is (are) encompassed within the metes and bounds of the invention." *See*, Office Action page 5.

Applicant respectfully disagrees and traverses this rejection. However, in order to expedite prosecution, Applicant has cancelled claims 1-29 and added claims 30-43, which do not include the language objected to. The new claims recite that "...at least one anti-RSV neutralizing antibody and at least one additional non-antibody anti-viral agent, wherein said composition prevents RSV infection." In view of the forgoing Applicant believes that the rejection has been obviated and, thus, Applicant respectfully requests that rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

C. The Examiner has rejected claim 6 because "the F epitope lacks antecedent basis." *See,* Office Action page 5. Applicant has cancelled claim 6, thus this rejection is now moot. In view of the above amendment, Applicant respectfully requests that rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

D. In addition, the Examiner has rejected claim 15 asserting that the claim provides no further limitation of the composition of claim one. *See,* Office Action page 5. Applicant has cancelled claim 15, thus this rejection is now moot. In view of the above amendment, Applicant respectfully requests that rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

E. The Examiner has further rejected claim 27 because the Examiner asserts that "[c]laim 27 is vague and indefinite in the absence of recitation of deposit accession number or other identifying structure or characteristic to clearly identify the antibody because, absent such recitation, it is not clear what structure and properties are encompassed by the named antibodies." *See*, Office Action page 6. Although claim 27 has been cancelled Applicant believes that the same rejection will be made for claim 33.

Applicant respectfully traverses this rejection.

Applicant respectfully points out that the specification defines Medi-493. For instance, on page 7, lines 20-25, of the specification it states "[t]he anti-viral antibody, such as high affinity antibody with the same antigenic specificity of an antibody as disclosed in U.S. Patent No. 5,824,307, especially the antibody whose heavy chain and light chain variable sequences are disclosed in Figure 7 and 8, respectively, thereof, or Medi-493..." Thus, a person skilled in the art would understand that Medi-493 is the antibody disclosed in figure 7 and 8 of the 5,824,307 patent. Therefore, Applicant asserts that Medi-493 is clearly defined. In view of the forgoing, Applicant requests that the rejection under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 102

A. The Examiner has rejected claims 1, 7, 9, 13-15, 19 and 20 under 35 U.S.C. § 102 (e) as being anticipated by Riggs (U.S. Pat. No. 6,110,463). In particular, the Examiner asserts that "Riggs *et al.* teach...and claim...compositions comprising the combination of a neutralizing antibody for *Crytosporidium parvum*, a second antibody specific for another antigen of the parasite, and/or mammalian colostrum which may

comprise additional antibodies, including neutralizing antibodies, specific for the parasite." *See*, Office Action page 6, last paragraph.

Applicant respectfully traverses this rejection.

Applicant respectfully points out that claims 1, 7, 9, 13-15, 19 and 20 have been cancelled, thus this rejection is now moot. In view of the above amendments, Applicant respectfully requests that rejection of claims under 35 U.S.C. § 102 (e) be reconsidered and withdrawn.

B. The Examiner has rejected claims 1-4, 6, 7, 9-13, 15, and 20 under 35 U.S.C. § 102 (b) as being anticipated by Crowe *et al.* The Examiner asserts that Crowe *et al.* "...teaches that it would be prudent to use a mixture of antibodies directed to different antigenic sites of the virus for treatment to prevent the emergence of antigenic escape mutants of the virus (see e.g. page 1390), thus teaching the composition as instantly claimed." *See*, Office Action page 7.

Applicant respectfully traverses this rejection.

Preliminarily Applicant respectfully points out that claims 1-4, 6, 7, 9-13, 15, and 20, have been cancelled.

Additionally, the pending claims now recite that the antiviral agent be a non-antibody agent. Support for this amendment can be found, for example, on page 6, lines 22-28 of the specification. Applicant respectfully points out that the Crow *et al.* reference does not disclose the treatment for respiratory diseases with an antibody and a non-antibody anti-viral agent that are in a composition. Thus, Crow *et al.* does not anticipate the new claims. In view of the above amendments, Applicant respectfully requests that rejection of claims under 35 U.S.C. § 102 (b) be reconsidered and withdrawn.

C. The Examiner has also rejected claims 1-4, 6, 7, 9-13, 15, 20, and 27 under 35 U.S.C. § 102 (b) as being anticipated by Johnson (U.S. Pat. No. 5,824,307). Specifically, the Examiner asserts that "Johnson teaches neutralizing anti-respiratory syncytial virus (RSV) F antigen antibodies by, *inter alia*, aerosol for treatment of RSV infections. The reference teaches administration of a plurality of antibodies against the same or different epitopes of the RSV F antigen (see e.g. col. 4), thus teaching the compositions as instantly claimed." *See*, Office Action page 7.

Applicant respectfully traverses this rejection.

Preliminarily, Applicant respectfully points out that claims 1-4, 6, 7, 9-13, 15, 20, and 27 have been cancelled.

Additionally, the pending claims now recite that the antiviral agent be a <u>non-antibody</u> agent. Support for this amendment can be found in the specification, for example, page 6, lines 22-28 of the specification. Applicant respectfully points out that the Johnson reference does not disclose the treatment for respiratory diseases with an antibody and a <u>non-antibody</u> anti-viral agent that are in a composition. Thus, Johnson does not anticipate the new claims. In view of the above, Applicant respectfully requests that rejection under 35 U.S.C. § 102 (b) be reconsidered and withdrawn.

<u>Rejection under 35 U.S.C. § 103</u>

The Examiner has rejected claims 1-7, 9-13, 15, 16, 20, and 27 under 35 U.S.C. § 103 (a) as being unpatentable over Hayden in view of Johnson (U.S. Pat. No. 5,824,307) or Crowe, *et al.* Specifically, the Examiner asserts that "Hayden teach combination treatments for respiratory virus infections, including combinations of amatadine with ribavirin, and combinations of neutralizing anti-RSV antibodies with ribavirin." The Examiner acknowledges that Hayden does not teach administration of anti-RSV antibody with anti-viral agents in a single composition. *See*, Office Action page 8.

Applicant respectfully disagrees with the rejection and traverses.

Preliminarily Applicant respectfully points out that claims 1-7, 9-13, 15, 16, 20, and 27 have been cancelled.

Applicant respectfully points out that the Patent Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995); *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, the Patent Office must first show that the prior art provided one of ordinary skill in the art with a motivation to make the claimed composition. Second, it must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the motivation and the reasonable expectation of success must be adequately founded in the prior art and not in the applicant's disclosure. Third, the Patent Office must show that the prior art teaches or suggests all the claimed limitations. *Manual of Patent Examining Procedure*, § 2143; *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). These criteria must be satisfied with factual and objective evidence found in the prior art: an examiner's conclusory statement cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002). Applicant respectfully submits that the Examiner has not met the burden of establishing a *prima facie* case of obviousness because Hayden, Crow *et al.* and Johnson do not suggest to those of ordinary skill in the art that they should make the claimed composition nor do they provide one of ordinary skill in the art with a reasonable expectation of success. In addition, the references do not teach all the claimed limitations in the pending claims.

Applicant points out that neither Hayden, Crow *et al.*, nor Johnson teach the administration of an antibody and non-antibody antiviral agents in a *single* composition. In addition, Hayden and Crowe *et al.* do not disclose prevention of RSV infection. The references merely disclose treatment of RSV once the subject has been infected. Thus, neither of those references disclose all of the limitations of the pending claims.

In addition, Hayden, on page 47, asserts that anti-RSV immunoglobulin should be given to high risk infants when RSV is identified in that community and to treat those with breakthrough illness with ribavrin. The implication is that anti-RSV immunoglobulin, alone, should be given to prevent infection. Thus, Hayden actually teaches away of the combination anti-RSV antibody and ribavarin for the prevention of RSV infection.

Also, Applicant points out that there is no expectation of success that such a composition would be viable or even possible. "Obvious to try" is not the legal standard under 35 U.S.C. § 103. The proper inquiry is whether the art suggested the invention at the time the invention was made, and whether the art would have provided one of ordinary skill in the art with a reasonable expectation of success. To reach the conclusion that the invention was obvious based on the cited references alone, one would have to use improper hindsight reasoning.

Additionally, the Examiner asserts that the Johnson *et al.* (J. Inf. Dis. 176: 1215, 1997), the Baummann *et al.* (WO 99/04814), and the Deen *et al.* (WO 98/19705) publications are pertinent to the applicant's disclosure. Applicant respectfully asserts that these publications are not pertinent to the pending claims

Johnson *et al.* does not disclose combination treatment with an antibody and non-antibody (see arguments above).

Baumann does not disclose anti-RSV antibodies in combination with non-antibody anti-microbial agents. The focus of this reference is Hepatitis B.

Deen *et al.* discloses therapeutic compositions comprising combinations of anti-RSV antibodies. In particular, the application does not disclose anti-RSV antibodies combined with a non-antibody antiviral agent. Thus, this reference would not be pertinent to the pending claims.

In view of the above, Applicant respectfully requests that rejection under 35 U.S.C. § 103 be reconsidered and withdrawn.

CONCLUSION

Applicant believes that this application is in condition for allowance, and it is therefore respectfully requested that the rejections be reconsidered and withdrawn and a favorable action is thereby solicited.

Respectfully submitted,

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